

Exhibit B

1 IN THE UNITED STATES DISTRICT COURT
2 SOUTHERN DISTRICT OF WEST VIRGINIA AT CHARLESTON
3 -----) Master File No.
4 IN RE: ETHICON, INC.,) 2:12-MD-02327
5 PELVIC REPAIR SYSTEM)
6 PRODUCTS LIABILITY LITIGATION) MDL 2327
7 -----)
8 THIS DOCUMENT RELATES TO) JOSEPH R. GOODWIN
9 PLAINTIFFS:) U.S. DISTRICT JUDGE
10)
11 Jeanie Holmes)
12 Case No. 2:12-cv-01206)
13)
14 Laura Waynick)
15 Case No. 2:12-cv-01151)
16)
17 Denise Burkhart)
18 Case No. 2:12-cv-01023)
19)
20 Pamela Free)
21 Case No. 2:12-cv-00423)
22)
23 Dorothy Baugher)
24 Case No. 2:12-cv-01053)
25)
26 Lisa Thompson)
27 Case No. 2:12-cv-01199)
28)
29 Rebecca Wheeler)
30 Case No. 2:12-cv-01088)
31)
32 Thelma Wright)
33 Case No. 2:12-cv-01091)
34)
35 Rocio-Herrera Nevarez)
36 Case No. 2:12-cv-01294)
37)
38 Debra A. and Donald)
39 Schnering)
40 Case No. 2:12-cv-01071)
41)
42 Margaret Kirkpatrick)
43 Case No. 2:12-cv-00746)
44 -----)
45 GENERAL DEPOSITION OF DENISE ELSER, M.D.

Denise Elser, M.D.

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| <p style="text-align: right;">Page 2</p> <p>1</p> <p>2</p> <p>3 The deposition of DENISE ELSER, M.D., called</p> <p>4 by the MDL Plaintiffs for examination, taken</p> <p>5 pursuant to the Federal Rules of Civil Procedure of</p> <p>6 the United States District Courts pertaining to the</p> <p>7 taking of depositions, taken before CORINNE T.</p> <p>8 MARUT, C.S.R. No. 84-1968, Registered Professional</p> <p>9 Reporter and a Certified Shorthand Reporter of the</p> <p>10 State of Illinois, at the Le Meridien Chicago -</p> <p>11 Oakbrook Center, Discovery Room, 2100 Spring Road,</p> <p>12 Oak Brook, Illinois, on March 30, 2016, commencing</p> <p>13 at 8:06 a.m.</p> <p>14</p> <p>15</p> <p>16</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> | <p style="text-align: right;">Page 4</p> <p>1 INDEX</p> <p>2 DENISE ELSER, M.D. EXAMINATION</p> <p>3 BY MR. FAES..... 5</p> <p>4</p> <p>5</p> <p>6 EXHIBITS</p> <p>7 ELSER DEPOSITION EXHIBIT MARKED FOR ID</p> <p>8 No. 1 Notice to Take Deposition of 8</p> <p style="padding-left: 40px;">Denise Elser, M.D.</p> <p>9</p> <p style="padding-left: 40px;">No. 2 General TVT and TVT-O Expert 11</p> <p style="padding-left: 40px;">Report of Denise M. Elser, M.D.</p> <p>10</p> <p>11 No. 3 Reliance List 12</p> <p>12 No. 4 curriculum vitae 27</p> <p>13</p> <p>14</p> <p>15</p> <p>16</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> |
| <p style="text-align: right;">Page 3</p> <p>1 APPEARANCES:</p> <p>2 ON BEHALF OF THE MDL PLAINTIFFS:</p> <p>3 WAGSTAFF & CARTMELL LLP</p> <p>4 4740 Grand Avenue, Suite 300</p> <p>5 Kansas City, Missouri 64112</p> <p>6 816-701-1100</p> <p>7 BY: ANDREW N. FAES, ESQ.</p> <p>8 afaes@wcllp.com</p> <p>9</p> <p>10 ON BEHALF OF PLAINTIFF JEANIE HOLMES:</p> <p>11 KABATECK BROWN KELLNER LLP</p> <p>12 Historic Fire Engine Co. No. 28 Building</p> <p>13 644 South Figueroa Street</p> <p>14 Los Angeles, California 90017</p> <p>15 213-217-5000</p> <p>16 BY: DREW R. FERRANDINI, ESQ.</p> <p>17 df@kbklawyers.com</p> <p>18</p> <p>19 ON BEHALF OF THE DEFENDANTS:</p> <p>20</p> <p>21 FRIDAY, ELDREDGE & CLARK, LLP</p> <p>22 400 West Capital Avenue, Suite 2000</p> <p>23 Little Rock, Arkansas 72201-3522</p> <p>24 501-376-2011</p> <p>BY: LAURA HENSLEY SMITH, ESQ.</p> <p>smith@fec.net</p> <p>REPORTED BY: CORINNE T. MARUT, C.S.R. No. 84-1968</p> | <p style="text-align: right;">Page 5</p> <p>1 (WHEREUPON, the witness was duly</p> <p>2 sworn.)</p> <p>3 DENISE ELSER, M.D.,</p> <p>4 called as a witness herein, having been first duly</p> <p>5 sworn, was examined and testified as follows:</p> <p>6 EXAMINATION</p> <p>7 BY MR. FAES:</p> <p>8 Q. Good morning, Doctor.</p> <p>9 A. Good morning.</p> <p>10 Q. My name is Andy Faes and I represent the</p> <p>11 Plaintiffs in this case. Do you understand that?</p> <p>12 A. Yes.</p> <p>13 Q. And we have never met before, is that</p> <p>14 correct?</p> <p>15 A. That's correct.</p> <p>16 Q. We are here today because you've been</p> <p>17 identified by Ethicon and Johnson & Johnson as a</p> <p>18 general causation expert related to the</p> <p>19 TVT-Retropubic product and the TVT-O in Wave 1 of</p> <p>20 the Ethicon MDL.</p> <p>21 Do you understand that?</p> <p>22 A. Yes.</p> <p>23 Q. Do you understand that I'm here today to</p> <p>24 ask you about your general opinions related to the</p> |

Denise Elser, M.D.

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| <p style="text-align: right;">Page 6</p> <p>1 TVT-Retropubic product and the TVT-O product 2 manufactured by Ethicon? 3 A. Yes. 4 Q. Now, when I refer to the TVT-Retropubic, 5 do you understand that I'm referring to the product 6 that was manufactured and initially brought to the 7 market in the United States in October of 1998? 8 A. Can I clarify? Can I ask you a 9 clarifying question about that, please. 10 Q. Sure. 11 A. So, the original product that was 12 brought out had a slight change in that the trocars 13 changed. So, I'm going to assume that you mean 14 either one of those first two products but not the 15 Exact. 16 Q. Okay. Is that your understanding in 17 this case? 18 A. Yes. 19 Q. And when I refer to the TVT-O product, 20 you understand that I'm referring to the product 21 that was manufactured and initially brought to the 22 market in January of 2004 in the United States, 23 correct? 24 A. Yes.</p> | <p style="text-align: right;">Page 8</p> <p>1 Q. The same question on the TVT-O, are your 2 opinions in this case, meaning the Wave 1 3 litigation, going to be related to both the 4 mechanical-cut versions and the laser-cut versions 5 of the TVT-O product? 6 A. Yes. 7 Q. Doctor, I'm going to hand you -- strike 8 that. 9 I take it that all of the opinions 10 related to the safety and efficacy of those 11 products, the TVT-O and the TVT, both the laser-cut 12 and mechanically-cut versions, are contained in 13 your report, your general report that you've 14 produced in this litigation? 15 A. Yes. 16 (WHEREUPON, a certain document was 17 marked Elser Deposition Exhibit 18 No. 1, Notice to Take Deposition of 19 Denise Elser, M.D.) 20 BY MR. FAES: 21 Q. Doctor, I'm going to hand you what's 22 been marked as Exhibit 1 to your deposition. Can 23 you tell me what that is. 24 A. This is a Notice to Take Deposition.</p> |
| <p style="text-align: right;">Page 7</p> <p>1 Q. And just as a point of clarification 2 since we were talking about the TVT-Retropubic 3 product, you're not here today to offer any 4 opinions about the TVT Exact product, correct? 5 A. Not unless you're asking about that. 6 Q. But you haven't -- as far as you're 7 aware, you haven't been disclosed as a general 8 expert by Ethicon and Johnson & Johnson on the 9 TVT-O Exact product at this time, correct? 10 A. Not that I know of. 11 Q. And you understand I take it from your 12 prior depositions that there is actually two 13 versions of the TVT-Retropubic product that 14 continue to be sold, one that has laser-cut mesh 15 and one with a mechanical-cut mesh, correct? 16 A. Yes. 17 Q. And the same is true of the TVT-O? 18 A. Yes. 19 Q. Are your opinions in this case, meaning 20 the Wave 1 litigation that you're identified in, 21 going to be related to both the mechanical-cut 22 versions of the TVT-Retropubic product and the 23 laser-cut versions? 24 A. Yes.</p> | <p style="text-align: right;">Page 9</p> <p>1 Q. Have you seen that document before 2 today? 3 A. I have. 4 Q. Have you brought -- strike that. 5 You see that there is various document 6 requests attached to that deposition. 7 Have you brought any -- any documents or 8 other items with you today in response to that 9 Notice? 10 A. No. 11 Q. Have you prepared a bill for your TVT-O 12 and TVT general report in this case? 13 A. No. 14 Q. Do you intend to submit a bill for the 15 work that you've done on that report in this case? 16 A. Yes. 17 Q. Can you estimate approximately how many 18 hours you've spent preparing the TVT-O and TVT 19 general report in this case? 20 A. Three to four hours. 21 Q. Just three to four hours? 22 A. To amend my prior report. 23 Q. And which report -- which prior report 24 were you working off of when you amended your TVT</p> |

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| <p style="text-align: right;">Page 10</p> <p>1 and TVT-O report that was served in Wave 1?</p> <p>2 A. My original general sling report. I</p> <p>3 don't know if you have a specific name for it or</p> <p>4 how you want me to describe it.</p> <p>5 Q. Do you know as you sit here today which</p> <p>6 case your previous TVT and TVT-O report that you</p> <p>7 were working off of to create the report in this</p> <p>8 case came from?</p> <p>9 A. I don't remember which one it was.</p> <p>10 Q. So, Doctor, you stated you spent</p> <p>11 approximately three to four hours creating the</p> <p>12 general report in this case or updating it.</p> <p>13 Was that three to four hours all time</p> <p>14 that you spent drafting the actual report?</p> <p>15 A. Looking for some literature and amending</p> <p>16 the report.</p> <p>17 Q. So, of the three to four hours that you</p> <p>18 spent looking -- strike that.</p> <p>19 First of all, when you say looking for</p> <p>20 literature, does the three to four hours include</p> <p>21 time just spent looking for literature or does it</p> <p>22 include time actually reviewing literature as well?</p> <p>23 A. Both.</p> <p>24 Q. So, the three to four hours that you</p> | <p style="text-align: right;">Page 12</p> <p>1 date you completed that report marked as</p> <p>2 Exhibit No. 2?</p> <p>3 A. Give me a minute to look at it.</p> <p>4 This would be the one that I prepared at</p> <p>5 the end of February, early March for this -- for</p> <p>6 these cases.</p> <p>7 Q. Can you be any more specific than that?</p> <p>8 Do you know when you actually finished that report</p> <p>9 other than -- can you be any more specific than the</p> <p>10 end of February or the beginning of March?</p> <p>11 A. I believe it was the last weekend in</p> <p>12 February.</p> <p>13 Q. And this report in front of you marked</p> <p>14 Exhibit No. 2, it contains all the opinions that</p> <p>15 you intend to offer on the TVT and TVT-O products,</p> <p>16 correct?</p> <p>17 A. At this time, although I may amend it if</p> <p>18 additional information becomes available.</p> <p>19 (WHEREUPON, a certain document was</p> <p>20 marked Elser Deposition Exhibit</p> <p>21 No. 3, Reliance List.)</p> <p>22 BY MR. FAES:</p> <p>23 Q. Doctor, I'm handing you what's been</p> <p>24 marked as Exhibit No. 3 to your deposition. Can</p> |
| <p style="text-align: right;">Page 11</p> <p>1 have spent in updating your report in the Wave 1</p> <p>2 cases includes time you spent drafting the report,</p> <p>3 searching for literature and reviewing literature,</p> <p>4 is that correct?</p> <p>5 A. Yes.</p> <p>6 Q. Of the three to four hours that you've</p> <p>7 spent in those activities, how many of those hours</p> <p>8 would you say were spent actually drafting the</p> <p>9 report?</p> <p>10 A. I can't -- I can't say exactly how much</p> <p>11 of that. Most of the time was spent reading the</p> <p>12 literature.</p> <p>13 Q. Doctor, I'm going to hand you what's</p> <p>14 been marked as Exhibit No. 2 to your deposition.</p> <p>15 (WHEREUPON, a certain document was</p> <p>16 marked Elser Deposition Exhibit</p> <p>17 No. 2, General TVT and TVT-O Expert</p> <p>18 Report of Denise M. Elser, M.D.)</p> <p>19 BY MR. FAES:</p> <p>20 Q. Can you tell me what that is?</p> <p>21 A. It's labeled as the general TVT/TVT-O</p> <p>22 expert report of mine.</p> <p>23 Q. Now, perhaps I missed it. I didn't see</p> <p>24 a date on that report. Can you tell me on what</p> | <p style="text-align: right;">Page 13</p> <p>1 you tell me what that is.</p> <p>2 A. Labeled as a reliance list in addition</p> <p>3 to materials referenced in the report for MDL</p> <p>4 Wave 1.</p> <p>5 Q. Does this exhibit -- strike that.</p> <p>6 Does this document marked as Exhibit 3</p> <p>7 contain all of the materials you have reviewed and</p> <p>8 relied upon in reaching your opinions regarding the</p> <p>9 TVT and the TVT-O in this case?</p> <p>10 A. Well, of course my knowledge base is</p> <p>11 based on many articles I have read over the years,</p> <p>12 but ones that I specifically cited in my report</p> <p>13 were included in this list.</p> <p>14 Q. Other than your knowledge base that</p> <p>15 you've required -- strike that.</p> <p>16 Other than your knowledge base that</p> <p>17 you've acquired over the years, is there anything</p> <p>18 other than the materials that are listed in this</p> <p>19 report marked as Exhibit 3 that you reviewed and</p> <p>20 relied upon in forming your opinions in this case?</p> <p>21 A. Not that I recall at this time.</p> <p>22 Q. Doctor, can you tell me if there are any</p> <p>23 depositions of any company witnesses, Ethicon</p> <p>24 company witnesses, on the reliance list marked as</p> |

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| <p style="text-align: right;">Page 14</p> <p>1 Exhibit No. 3?</p> <p>2 A. Can you say again? Depositions of whom?</p> <p>3 MR. FAES: Can we have the Court Reporter read</p> <p>4 back the question, please.</p> <p>5 (WHEREUPON, the record was read</p> <p>6 by the reporter as requested as</p> <p>7 follows: Q. Doctor, can you tell</p> <p>8 me if there are any depositions of</p> <p>9 any company witnesses, Ethicon</p> <p>10 company witnesses, on the reliance</p> <p>11 list marked as Exhibit No. 3?)</p> <p>12 BY THE WITNESS:</p> <p>13 A. By that you mean employees of Ethicon?</p> <p>14 BY MR. FAES:</p> <p>15 Q. Correct. Let me see if I can ask it a</p> <p>16 different -- actually, I will let you answer the</p> <p>17 question. Never mind.</p> <p>18 A. Okay. I don't see depositions of</p> <p>19 employees on here.</p> <p>20 Q. Okay. So, let me ask you this. Have</p> <p>21 you reviewed or relied upon any company depositions</p> <p>22 of -- strike that.</p> <p>23 Doctor, have you reviewed or relied upon</p> <p>24 any depositions of any Ethicon company witnesses in</p> | <p style="text-align: right;">Page 16</p> <p>1 expert and some cases it's both. Do you understand</p> <p>2 that?</p> <p>3 A. Correct. Okay. I did not count the</p> <p>4 number. I did not understand it to be 17, but that</p> <p>5 sounds reasonable.</p> <p>6 Q. You have no reason to disagree as you</p> <p>7 sit here today that the number of cases that</p> <p>8 you're -- have been designated on or working on in</p> <p>9 Wave 1 is 17?</p> <p>10 A. Correct.</p> <p>11 Q. Prior to the 17 Wave 1 cases that you're</p> <p>12 working on, you've consulted as an expert for</p> <p>13 Ethicon in litigation in seven other pelvic mesh</p> <p>14 cases, is that correct?</p> <p>15 A. Again, I hadn't counted, but that sounds</p> <p>16 about right.</p> <p>17 Q. Well, let's go through them. You have</p> <p>18 worked on the Corbett case, correct?</p> <p>19 A. Yes.</p> <p>20 Q. You have worked on the Bellew case,</p> <p>21 correct?</p> <p>22 A. Yes.</p> <p>23 Q. You have worked on the Budke case,</p> <p>24 correct?</p> |
| <p style="text-align: right;">Page 15</p> <p>1 forming your opinions in this case?</p> <p>2 A. I have read them, but I did not cite</p> <p>3 them in my report.</p> <p>4 Q. Which ones have you read? Where would I</p> <p>5 get a list of the company depositions that</p> <p>6 you've -- that you've read?</p> <p>7 A. That I would have to look and see which</p> <p>8 ones I have in my file, but I was not planning to</p> <p>9 specifically cite them or rely on them. I did not</p> <p>10 rely on them for this report.</p> <p>11 Q. So, even though you've reviewed some</p> <p>12 depositions of Ethicon company witnesses, there is</p> <p>13 none that you intend to rely upon in forming your</p> <p>14 opinions in this case, is that correct?</p> <p>15 A. Yes.</p> <p>16 Q. Doctor, would you agree that you've been</p> <p>17 designated either as a general expert or a specific</p> <p>18 expert or both in 17 Wave 1 cases?</p> <p>19 A. Well, I think we have to make a</p> <p>20 distinction between what is designated on the list</p> <p>21 and which ones I've reviewed.</p> <p>22 Q. And you understand that on some cases</p> <p>23 you've been designated just as a general expert,</p> <p>24 some cases you've been designated as a specific</p> | <p style="text-align: right;">Page 17</p> <p>1 A. Yes.</p> <p>2 Q. You have worked on the Edwards case,</p> <p>3 correct?</p> <p>4 A. Yes.</p> <p>5 Q. You have worked on the Huskey case,</p> <p>6 correct?</p> <p>7 A. Yes.</p> <p>8 Q. You've worked on the Wicker case,</p> <p>9 correct?</p> <p>10 A. Yes.</p> <p>11 Q. You have worked on the Carlino case,</p> <p>12 correct?</p> <p>13 A. Yes.</p> <p>14 Q. So, that's seven cases, right?</p> <p>15 A. That's seven.</p> <p>16 Q. Are there any other ones that you can</p> <p>17 think of sitting here today that you've worked not</p> <p>18 including the Wave 1 cases?</p> <p>19 A. No.</p> <p>20 Q. So, if you have worked on seven cases</p> <p>21 prior to Wave 1 and you've been designated on 17</p> <p>22 cases, you'd agree that you've worked on 24 cases</p> <p>23 for -- at least 24 cases for Ethicon as a</p> <p>24 litigation consultant, correct?</p> |

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| <p style="text-align: right;">Page 18</p> <p>1 A. Well, to be very specific, I've not 2 worked on all of the 17 listed. I am listed as a 3 general expert. That does not mean that I have yet 4 worked specifically on those cases. 5 Q. But you understand -- do you understand 6 that when you're declared as a general expert in a 7 case and you file a general report such as the 8 report marked in front of you, Exhibit No. 2, you 9 don't consider yourself to have worked on that case 10 as a general expert? 11 A. Well, this must be legal semantics. 12 It's not a language I usually use. I have not 13 specifically worked on those cases yet. I have 14 worked on a general report being applied to these 15 cases. 16 Q. Okay. Well, let me ask it this way. 17 Assuming that filing a general report in a case is 18 deemed to be worked or retained as an expert on 19 this case, you would agree that at this point you 20 have worked on at least 24 cases for Ethicon in 21 pelvic mesh litigation, correct? 22 A. Yes. 23 MS. SMITH: You have used "worked on," 24 "retained"; and then you just changed it to just</p> | <p style="text-align: right;">Page 20</p> <p>1 Q. Yes. 2 A. It would be about six to seven hours per 3 case. 4 (WHEREUPON, there was a short 5 interruption.) 6 BY MR. FAES: 7 Q. Just so I understand your testimony, you 8 estimate at this time that you have spent 9 approximately six to seven hours on each of the 12 10 cases where you're designated as a specific -- 11 case-specific expert? 12 A. Yes. 13 Q. Is your hourly rate for records review 14 still \$500 an hour? 15 A. No. It's now 650. 16 Q. When did that change? 17 A. January 1. 18 Q. Of this year? 19 A. Yes. 20 Q. That's a \$150 an hour increase, correct? 21 A. Yes. 22 Q. Why did you make that change? 23 A. January 1? 24 Q. I said why. Why. Sorry.</p> |
| <p style="text-align: right;">Page 19</p> <p>1 "worked on." 2 MR. FAES: Okay. 3 MS. SMITH: I think -- that's the -- 4 "retained" is I think different. 5 MR. FAES: Is that an objection? 6 MS. SMITH: Yes. 7 MR. FAES: Okay. Duly noted. 8 BY MR. FAES: 9 Q. Doctor, have you been paid for each of 10 the seven cases that you worked on prior to Wave 1? 11 And I can go through the list again if you want one 12 by one but -- 13 A. I have. 14 Q. And you expect to be paid for the 17 15 Wave 1 cases that you're working on for Ethicon, 16 correct? 17 MS. SMITH: Object to the form. 18 BY THE WITNESS: 19 A. Yes. 20 BY MR. FAES: 21 Q. Do you have an estimate of how much time 22 you've spent on each of the case-specific reports 23 that you've issued in the Wave 1 case? 24 A. Including since the report was written?</p> | <p style="text-align: right;">Page 21</p> <p>1 A. Why. 2 Q. My apologies. Why did you make that 3 change? 4 A. As I've gained more experience in 5 reviewing these cases and writing reports and 6 surveying what other experts were being paid, I 7 felt an increase was reasonable. 8 Q. Is your hourly rate for depositions 9 still \$600 an hour for the first six hours? 10 A. No, that increased as well. 11 Q. What's that right now? 12 A. I don't have it in front of me. It 13 probably went up by the same increment. 14 Q. Is that contained anywhere within your 15 report that we could find? 16 A. I submitted it to someone, but I can 17 easily produce that later for you. 18 Q. Okay. 19 MR. FAES: I'd ask that counsel get us that 20 information because I did not see it in the expert 21 report and I don't believe it's been disclosed 22 anywhere. 23 BY MR. FAES: 24 Q. Is your rate for trial testimony still</p> |

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| <p style="text-align: right;">Page 22</p> <p>1 \$4,000 a day?</p> <p>2 A. No.</p> <p>3 Q. And what is it now?</p> <p>4 A. 8,000.</p> <p>5 Q. And I assume that your answer to why you</p> <p>6 changed that rate would be the same as the answer</p> <p>7 for why you changed your hourly rate for records</p> <p>8 review?</p> <p>9 A. Yes.</p> <p>10 Q. All of the work that you've done in the</p> <p>11 12 cases in Wave 1, would that have been done after</p> <p>12 January 1 of this year and subject to your new 650</p> <p>13 an hour review rate?</p> <p>14 A. Yes.</p> <p>15 Q. And the time you spent actually writing</p> <p>16 the report, that's also billed at your hourly</p> <p>17 review rate of \$650 an hour, is that correct?</p> <p>18 A. Correct.</p> <p>19 Q. Do you recall how much you've billed in</p> <p>20 the Wicker case?</p> <p>21 A. No.</p> <p>22 Q. Do you recall if it was \$21,000?</p> <p>23 A. I don't recall what it was.</p> <p>24 Q. Do you recall what you billed in the</p> | <p style="text-align: right;">Page 24</p> <p>1 in that case?</p> <p>2 A. To my best recollection, it was</p> <p>3 \$80,000ish.</p> <p>4 Q. Do you recall approximately how many</p> <p>5 hours you spent on that case?</p> <p>6 A. No.</p> <p>7 MR. FAES: Counsel, just for the record we</p> <p>8 would request that that information be produced.</p> <p>9 And just so you're aware, we are in</p> <p>10 discussions with counsel with regard to kind of a</p> <p>11 global agreement with our experts and their experts</p> <p>12 regarding all the payments they have received so</p> <p>13 far in this case. But we believe we are entitled</p> <p>14 to that information, and we would ask that it be</p> <p>15 produced.</p> <p>16 BY MR. FAES:</p> <p>17 Q. Doctor, could you take a look at your</p> <p>18 reliance list again. What exhibit number is that?</p> <p>19 A. 3.</p> <p>20 Q. As before, was this reliance list</p> <p>21 created by your attorneys?</p> <p>22 MS. SMITH: Object to form.</p> <p>23 BY THE WITNESS:</p> <p>24 A. With edits by myself.</p> |
| <p style="text-align: right;">Page 23</p> <p>1 Bellew case?</p> <p>2 A. No.</p> <p>3 Q. Do you recall whether or not it was in</p> <p>4 excess of \$74,000?</p> <p>5 A. I don't.</p> <p>6 Q. Do you recall how much you billed in the</p> <p>7 Corbett case?</p> <p>8 A. No.</p> <p>9 Q. Do you recall if it was in excess of</p> <p>10 \$31,000?</p> <p>11 A. I don't recall.</p> <p>12 Q. Do you recall what you billed in the</p> <p>13 Budke case?</p> <p>14 A. No.</p> <p>15 Q. Do you recall if the bill in that case</p> <p>16 was greater than \$60,000?</p> <p>17 A. I don't.</p> <p>18 Q. Do you recall what you billed in the</p> <p>19 Edwards case?</p> <p>20 A. No.</p> <p>21 Q. Do you -- have you -- you said you have</p> <p>22 submitted your bill in the Carlino case, correct?</p> <p>23 A. Yes.</p> <p>24 Q. Do you recall what your total bill was</p> | <p style="text-align: right;">Page 25</p> <p>1 BY MR. FAES:</p> <p>2 Q. So, you would agree that this list was</p> <p>3 primarily created by your attorneys in this case</p> <p>4 but you reviewed it and edited it as necessary, is</p> <p>5 that correct?</p> <p>6 MS. SMITH: Object to form. We're not</p> <p>7 representing her for the record. We are not her</p> <p>8 attorneys.</p> <p>9 BY MR. FAES:</p> <p>10 Q. Well, let me see if I can state it</p> <p>11 another way. I will strike that and ask a</p> <p>12 different question.</p> <p>13 Would you agree that attorneys for</p> <p>14 Ethicon and Johnson & Johnson primarily created</p> <p>15 that list but you reviewed it and made edits to it</p> <p>16 as necessary?</p> <p>17 A. Yes.</p> <p>18 Q. Doctor, were you given free access to</p> <p>19 all of the Ethicon and Johnson & Johnson company</p> <p>20 documents in this case?</p> <p>21 MS. SMITH: Object to form.</p> <p>22 BY THE WITNESS:</p> <p>23 A. I wouldn't know what all the documents</p> <p>24 are. So, I couldn't answer if I had free access.</p> |

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| <p style="text-align: right;">Page 26</p> <p>1 BY MR. FAES:</p> <p>2 Q. Well, let me see if I can ask it a</p> <p>3 different way.</p> <p>4 Do you believe that if you had asked to</p> <p>5 see any particular Ethicon or Johnson & Johnson</p> <p>6 company documents, if you made that request of</p> <p>7 Ethicon and Johnson & Johnson's attorneys, do you</p> <p>8 believe that request would be granted?</p> <p>9 MS. SMITH: Object to the form.</p> <p>10 BY THE WITNESS:</p> <p>11 A. I don't know if there are certain</p> <p>12 documents they have that are confidential that I</p> <p>13 would be denied, but I did not ask to see any. So</p> <p>14 I find that question not applicable.</p> <p>15 BY MR. FAES:</p> <p>16 Q. Okay. So, just to make sure I</p> <p>17 understand your testimony. You have not asked</p> <p>18 specifically to see any Ethicon or</p> <p>19 Johnson & Johnson internal company documents in --</p> <p>20 strike that.</p> <p>21 Just to be clear, you have not asked to</p> <p>22 see any internal Ethicon or Johnson & Johnson</p> <p>23 company documents in order to form your opinions in</p> <p>24 this case regarding the TVT and TVT-O, correct?</p> | <p style="text-align: right;">Page 28</p> <p>1 with regard to the date, CV, most currently and</p> <p>2 updated CV that you've prepared?</p> <p>3 A. Well, the address is blacked out. So, I</p> <p>4 can't tell because we moved in December. But I</p> <p>5 think that would be the most updated.</p> <p>6 Q. And it's fair to say you will probably</p> <p>7 have to make another update soon to correct the</p> <p>8 date, right?</p> <p>9 A. Yes. Thanks for pointing that out.</p> <p>10 Q. Now, in November of this year you -- was</p> <p>11 that the last time you were deposed with regard to</p> <p>12 TVT and TVT-O that you recall or November of last</p> <p>13 year?</p> <p>14 MS. SMITH: You're doing the same thing.</p> <p>15 MR. FAES: Strike that.</p> <p>16 THE WITNESS: I have set everybody off with</p> <p>17 that date problem.</p> <p>18 BY MR. FAES:</p> <p>19 Q. In November of last year you were</p> <p>20 deposed regarding the TVT and TVT-O device,</p> <p>21 correct?</p> <p>22 A. I don't remember the date, but that</p> <p>23 seems like about the time I had the last</p> <p>24 deposition.</p> |
| <p style="text-align: right;">Page 27</p> <p>1 A. That's correct.</p> <p>2 Q. You didn't feel that there was anything</p> <p>3 in Ethicon or Johnson & Johnson's internal files</p> <p>4 that could be helpful to you in reaching your</p> <p>5 opinions in this case on whether or not the TVT or</p> <p>6 TVT-O is defectively designed?</p> <p>7 MS. SMITH: Object to form.</p> <p>8 BY THE WITNESS:</p> <p>9 A. Correct.</p> <p>10 BY MR. FAES:</p> <p>11 Q. Doctor, I'm going to hand you what's</p> <p>12 been marked as Exhibit No. 4 to your deposition.</p> <p>13 (WHEREUPON, a certain document was</p> <p>14 marked Elser Deposition Exhibit</p> <p>15 No. 4, curriculum vitae.)</p> <p>16 BY MR. FAES:</p> <p>17 Q. Can you tell me what that is?</p> <p>18 A. It's my CV dated December -- oh, 2016.</p> <p>19 I think that should be 2015.</p> <p>20 Q. Was that CV actually updated in</p> <p>21 December of 2015? Is that the last time it was</p> <p>22 updated?</p> <p>23 A. Yes.</p> <p>24 Q. Is that your current, albeit incorrect</p> | <p style="text-align: right;">Page 29</p> <p>1 Q. Do you recall if that was the last time</p> <p>2 you were deposed regarding the TVT and TVT-O</p> <p>3 device?</p> <p>4 A. I believe it was.</p> <p>5 Q. Now, in November of last year you</p> <p>6 testified that you were still using the Elevate</p> <p>7 device to treat pelvic organ prolapse, correct?</p> <p>8 A. Yes.</p> <p>9 Q. Is that -- that's no longer the case,</p> <p>10 correct?</p> <p>11 A. Well, we have a few more on the shelf,</p> <p>12 but that will no longer be the case in the very</p> <p>13 near future.</p> <p>14 Q. And that's because the Elevate is no</p> <p>15 longer going to be available from the manufacturer,</p> <p>16 correct?</p> <p>17 A. That's correct.</p> <p>18 Q. Do you plan -- strike that.</p> <p>19 When the Elevate is no longer available,</p> <p>20 i.e., when the stock runs out, do you plan to use</p> <p>21 any other mesh kits for the treatment of pelvic</p> <p>22 organ prolapse?</p> <p>23 MS. SMITH: Wait a minute. This is TVT and</p> <p>24 TVT-O. We are not getting into pelvic organ</p> |

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| <p style="text-align: right;">Page 30</p> <p>1 prolapse. That's another day. 2 MR. FAES: Actually, it's not and it's 3 relevant to the opinions in our case because it's 4 pelvic mesh made of polypropylene. I promise you 5 I'm not going to go that deep into it, but I think 6 these questions are appropriate. 7 She relies on her clinical experience to 8 form her opinions regarding the TVT and TVT-O and 9 her experience with polypropylene mesh inserted in 10 the pelvic space is relevant to her opinions. So, 11 I'm going to let the question stand. 12 I don't know if you're going to instruct 13 the witness not to answer or not. That's up to 14 you. If you instruct the witness not to answer, 15 then we might have to come back and take it up with 16 Judge Eifert. 17 But that's my position is that a limited 18 number of questions on her clinical use is 19 appropriate. She's relying on her clinical 20 experience for her opinions in this case and that 21 clinical experience involves the use of 22 polypropylene in the vagina, which includes pelvic 23 organ prolapse mesh. 24 MS. SMITH: Under your theory, any question</p> | <p style="text-align: right;">Page 32</p> <p>1 urinary incontinence -- strike that. 2 Other than the Elevate device, has your 3 use of polypropylene mesh devices for the treatment 4 of stress urinary incontinence or pelvic organ 5 prolapse changed since you were last deposed in 6 November of 2015? 7 A. Well, I've also been using the MiniArc 8 sling, and that will no longer be available. So, 9 my practice will be changing. 10 Q. How long have you been using the 11 MiniArc? 12 A. For a few years. I don't know exactly 13 how long. 14 Q. Okay. Do you know what you plan to use 15 instead in place of the MiniArc when it no longer 16 becomes available to treat your patients with 17 stress urinary incontinence? 18 A. No, I have not made that decision yet. 19 Q. Is Exact -- is the TVT -- strike that. 20 Is the TVT Exact still your sling of 21 choice for the treatment of stress urinary 22 incontinence? 23 A. That is the one I use most often. 24 Q. So, is the answer yes, it's your -- it's</p> |
| <p style="text-align: right;">Page 31</p> <p>1 regarding any pelvic organ prolapse would be 2 appropriate, and I don't think that's what the 3 agreement was in this limited updated deposition. 4 I will let her answer that one and 5 hopefully that will be the end of it. 6 BY MR. FAES: 7 Q. You need the question read back to you, 8 Doctor? 9 A. Yes, please. 10 (WHEREUPON, the record was read 11 by the reporter as requested as 12 follows: Q. When the Elevate is 13 no longer available, i.e., when the 14 stock runs out, do you plan to use 15 any other mesh kits for the 16 treatment of pelvic organ 17 prolapse?) 18 BY THE WITNESS: 19 A. I haven't decided yet whether it would 20 be a mesh kit or I will formulate my own mesh to 21 place vaginally. 22 BY MR. FAES: 23 Q. Has -- other than the Elevate, has your 24 use of the devices for the treatment of stress</p> | <p style="text-align: right;">Page 33</p> <p>1 your sling of choice for most patients? 2 A. For most patients. 3 Q. Okay. You have testified before that 4 you do not use the Gynemesh PS product, correct? 5 A. By that you mean the freestanding mesh 6 product? 7 Q. Yes. 8 A. I have used it in rare occasions 9 recently. 10 Q. When have you used it recently? 11 A. When there was no mesh kit available at 12 a hospital and I wanted a vaginal mesh. 13 Q. So, you used it for pelvic organ 14 prolapse, not for stress urinary incontinence, 15 correct? 16 A. Correct. 17 Q. Have you ever used the Gynemesh PS 18 product for the treatment of stress urinary 19 incontinence? 20 A. I don't believe so. 21 Q. Do you have any reason to believe that 22 the Gynemesh PS product would not be effective for 23 the treatment of stress urinary incontinence? 24 MS. SMITH: Object to form.</p> |

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| <p style="text-align: right;">Page 34</p> <p>1 BY THE WITNESS:</p> <p>2 A. Yes.</p> <p>3 BY MR. FAES:</p> <p>4 Q. And why is that?</p> <p>5 A. Because of how thin it is and the size</p> <p>6 of the pores.</p> <p>7 Q. So, you believe that the Gynemesh PS</p> <p>8 product is too thin and the pores are too large to</p> <p>9 effectively treat stress urinary incontinence, is</p> <p>10 that correct?</p> <p>11 A. They may be and I've not considered</p> <p>12 using it for incontinence.</p> <p>13 Q. Have you reviewed or are you aware of</p> <p>14 any clinical literature that actually studies the</p> <p>15 Gynemesh PS used for the treatment of stress</p> <p>16 urinary incontinence?</p> <p>17 A. I would have to check my list. I don't</p> <p>18 recall anything at this moment.</p> <p>19 Q. But sitting here today, if there are</p> <p>20 studies out there that have looked at the use of</p> <p>21 Gynemesh PS for the treatment of stress urinary</p> <p>22 incontinence, it's fair to say that sitting here</p> <p>23 today you don't know what the results of those</p> <p>24 studies are, correct?</p> | <p style="text-align: right;">Page 36</p> <p>1 that surgery that's occurred within the last year?</p> <p>2 A. I did not review the IFU in the last</p> <p>3 year.</p> <p>4 Q. Do you know whether or not Gynemesh PS</p> <p>5 is still indicated for transvaginal placement?</p> <p>6 A. According to the IFU? No, I have not</p> <p>7 reviewed it.</p> <p>8 Q. So, you don't know sitting here today</p> <p>9 one way or the other if according to the IFU the</p> <p>10 Gynemesh PS is indicated for transvaginal</p> <p>11 placement?</p> <p>12 A. No.</p> <p>13 Q. Assuming that the Gynemesh PS is no</p> <p>14 longer indicated for transvaginal placement, given</p> <p>15 that it is made from the same raw Prolene</p> <p>16 polypropylene material as what the TVT sling is</p> <p>17 made from, would that have any effect or bearing on</p> <p>18 your decisions or on your opinions in this case?</p> <p>19 MS. SMITH: Object to form.</p> <p>20 BY THE WITNESS:</p> <p>21 A. No.</p> <p>22 BY MR. FAES:</p> <p>23 Q. So, assuming that the FDA required</p> <p>24 Ethicon and Johnson & Johnson to remove the</p> |
| <p style="text-align: right;">Page 35</p> <p>1 A. Right.</p> <p>2 Q. Do you know that the Gynemesh PS product</p> <p>3 is made from the same Prolene polypropylene raw</p> <p>4 material as the TVT sling?</p> <p>5 A. I imagine it is, yes.</p> <p>6 Q. Sorry. I need to backtrack a minute</p> <p>7 just so I don't forget to ask you later.</p> <p>8 How many times would you say that you</p> <p>9 have used Gynemesh PS in the past year?</p> <p>10 A. Once or twice.</p> <p>11 Q. And do you recall if it was once or</p> <p>12 twice or you just don't know sitting here today if</p> <p>13 it was once or twice?</p> <p>14 A. Most likely just once that I had to use</p> <p>15 it or I decided to use it.</p> <p>16 Q. Do you recall in that case whether or</p> <p>17 not you implanted the Gynemesh PS product</p> <p>18 transvaginally or abdominally?</p> <p>19 A. Vaginally.</p> <p>20 Q. Do you recall if that occurred before or</p> <p>21 after May of 2015?</p> <p>22 A. I don't. I think it was after.</p> <p>23 Q. Do you recall if you reviewed the</p> <p>24 Gynemesh PS IFU prior to using the Gynemesh PS in</p> | <p style="text-align: right;">Page 37</p> <p>1 transvaginal use indication as a condition of</p> <p>2 keeping it on the market, that wouldn't affect your</p> <p>3 opinion in any way regarding the safety and</p> <p>4 efficacy of the TVT and TVT-O even though they're</p> <p>5 made from the same raw material?</p> <p>6 MS. SMITH: Object to form.</p> <p>7 THE WITNESS: That means I'm still answering,</p> <p>8 right?</p> <p>9 MS. SMITH: Yes.</p> <p>10 BY THE WITNESS:</p> <p>11 A. No, it would not.</p> <p>12 BY MR. FAES:</p> <p>13 Q. You don't think the fact that the</p> <p>14 transvaginal use indication has been removed for</p> <p>15 the Gynemesh PS is an indication that the FDA</p> <p>16 thinks that the material may not be safe for</p> <p>17 placement in vaginal tissues?</p> <p>18 MS. SMITH: Object to form.</p> <p>19 BY THE WITNESS:</p> <p>20 A. No.</p> <p>21 BY MR. FAES:</p> <p>22 Q. You don't think the fact that the</p> <p>23 transvaginal use indication has been removed from</p> <p>24 the Gynemesh PS IFU is an indication that Ethicon</p> |

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| <p style="text-align: right;">Page 38</p> <p>1 feels the material may not be safe for use in 2 vaginal tissues? 3 MS. SMITH: Object to form. 4 BY THE WITNESS: 5 A. I don't know what they think. 6 BY MR. FAES: 7 Q. Doctor, are you currently peer reviewer 8 on any peer-reviewed journals? 9 A. Yes. 10 Q. Which one? 11 A. The Green Journal, American Journal of 12 Ob-Gyn, International Urogynecologic Journal and 13 the Female Pelvic Medicine Journal. 14 Q. Any others? 15 A. Not that I recall. 16 Q. Do you understand the need for reviewers 17 and authors to disclose conflicts of interests when 18 publishing clinical data in a peer-reviewed medical 19 journal? 20 A. I understand. 21 Q. Do you understand that they do that 22 because without that disclosure there can be an 23 impression of bias, correct? 24 A. Yes.</p> | <p style="text-align: right;">Page 40</p> <p>1 or any study to determine how stiff or whether 2 there is a difference in stiffness between 3 laser-cut mesh and mechanically-cut mesh? 4 A. I have not done such a study. 5 Q. Have you ever seen any internal Ethicon 6 studies or documents related to the laser-cut mesh 7 being stiffer than mechanically-cut mesh? 8 A. I have at some time seen such documents. 9 Q. And how did those documents inform your 10 opinion -- opinions in this case? 11 A. They have not. 12 Q. So, you gave them no weight in 13 forming -- strike that. 14 So, the internal and -- strike that 15 again. 16 The internal Ethicon studies or 17 documents related to laser-cut mesh being stiffer 18 than mechanically-cut mesh, you gave those 19 documents no weight or bearing in forming your 20 opinions and conclusions in this case regarding the 21 TVT-O and TVT? 22 MS. SMITH: Object to form. 23 BY THE WITNESS: 24 A. Right. What happens in the lab in an</p> |
| <p style="text-align: right;">Page 39</p> <p>1 Q. Would you agree that it's a pretty 2 fundamental concept in the medical literature that 3 anything that can even appear to be a bias should 4 be disclosed? 5 MS. SMITH: Object to form. 6 BY THE WITNESS: 7 A. Can you say that again? 8 BY MR. FAES: 9 Q. Would you agree with me that it's a 10 pretty fundamental concept with regard to 11 peer-reviewed medical literature that anything that 12 can even appear to be a bias should be disclosed? 13 MS. SMITH: Object to form. 14 BY THE WITNESS: 15 A. I think that's too broad of a statement. 16 BY MR. FAES: 17 Q. Okay. Where was I wrong? 18 A. Well, it can get extremely detailed. 19 So, if you own mutual funds that own stocks of 20 medical device, are you expected to disclose that? 21 No. Would someone think that's a bias? They 22 might. But at this time certain things are not 23 within the guidelines of what is disclosed. 24 Q. Doctor, have you ever done any research</p> | <p style="text-align: right;">Page 41</p> <p>1 artificial setting is not important to me compared 2 to how the sling reacts clinically and how it 3 performs. 4 BY MR. FAES: 5 Q. Okay. My question was actually a little 6 bit different than that. 7 My question was: Did you give the 8 internal Ethicon studies or documents related to 9 the laser-cut mesh being stiffer or not stiffer 10 than the mechanically-cut mesh any weight or 11 bearing in forming your opinions in this case 12 regarding the TVT or TVT-O device? 13 A. No. 14 MS. SMITH: Object to form. 15 BY MR. FAES: 16 Q. Are you aware of how long it took 17 Ethicon to get the TVT-O product to market? 18 A. No, I am not. 19 Q. So, it's fair to say you haven't 20 reviewed any internal Ethicon documents discussing 21 that, or at least if you have, you can't recall 22 them as you sit here today? 23 A. That would be correct. 24 Q. Have you ever published any of the</p> |

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| <p style="text-align: right;">Page 42</p> <p>1 opinions that you're giving in this litigation in a 2 peer-reviewed medical journal? 3 MS. SMITH: Object to form. 4 BY THE WITNESS: 5 A. I think "any" is a broad statement. I 6 have written about a general article on 7 incontinence and would have included some opinions 8 on slings. So, I don't -- I have not written 9 specifically about, say, my general report in this. 10 BY MR. FAES: 11 Q. Let me ask it a different way because 12 obviously you have been deposed many times before. 13 Have you ever published any of the 14 opinions you are giving in this litigation in a 15 peer-reviewed medical journal within the last two 16 years? 17 A. I don't think so. 18 Q. Okay. Doctor, I want to ask you a 19 couple questions about specific things that you 20 have said in your report in this case. The first 21 thing I'm going to ask you about is on page 36. 22 You don't necessarily need to look at it, but I 23 just wanted you to be aware of where I am so you 24 can follow along if you want.</p> | <p style="text-align: right;">Page 44</p> <p>1 A. I would have to double-check that. But, 2 yes, that's what I believed. 3 Q. Do you have an opinion on whether or not 4 a mesh needs to be multi-filament or monofilament 5 to be considered a Type 1 mesh under the Amid 6 standards? 7 A. The Type 1 mesh is monofilament. 8 Q. Well, you know the Ultrapro mesh was 9 used in the Prolift+M product for the treatment of 10 pelvic organ prolapse, correct? 11 MS. SMITH: Object to form. 12 BY THE WITNESS: 13 A. Yes. 14 BY MR. FAES: 15 Q. Okay. It also states in this opinion 16 that the Ultrapro mesh was tested and failed as a 17 sling in cadaver labs. 18 What cadaver labs are you referring to? 19 A. So, I will have to take -- amend what I 20 said earlier about company documents because I did 21 get this information from a company document that 22 there was a cadaver lab and surgeons were asked to 23 rate what they thought of Ultrapro as using it as a 24 sling in cadavers.</p> |
| <p style="text-align: right;">Page 43</p> <p>1 On page 36 of your report you state that 2 "Unlike the multi-filament mesh like the Ultrapro, 3 which was tested and failed as a sling in cadaver 4 labs, was rejected by two-thirds of surgeons as a 5 sling concept, and has not been studied like the 6 TVT-O or TVT with the volume of RCTs, metaanalyses, 7 systematic reviews and other long-term follow-up, 8 the 1.1 centimeter strip of macroporous, 9 monofilament polypropylene mesh used in TVT and 10 TVT-O is the most suitable for use in treating 11 SUI." 12 Do you see that? 13 A. Yes. 14 Q. I may have left out a word or two in my 15 reading, but did any errors in my reading affect 16 the substance of that opinion? 17 A. I don't think so. 18 Q. Okay. Now, you state that the Ultrapro 19 is a multi-filament mesh. Is that just an error or 20 do you believe that the Ultrapro mesh is a 21 multi-filament mesh? 22 A. That was what I believed. 23 Q. Do you still believe it's a 24 multi-filament mesh as you sit here today?</p> | <p style="text-align: right;">Page 45</p> <p>1 Q. Do you recall the date of those cadaver 2 labs where it stated it failed as a sling? 3 A. I don't. 4 Q. Do you recall the reasons why those 5 cadaver labs stated that the Ultrapro sling failed? 6 A. One reason was the inability to 7 sterilize the Ultrapro in the plastic sheath 8 because it stuck to the sheath and the sheath could 9 not be removed without distorting the sling. 10 Q. Do you know whether or not Ethicon 11 engineers took the results from the cadaver labs 12 that you saw and made changes to the sling product 13 using the Ultrapro and ultimately fixed that 14 problem? 15 A. I don't know that. 16 Q. If that is -- assuming that is indeed 17 the case, would that change your opinion in this 18 case that the sling with the Ultrapro mesh was 19 rejected and -- strike that. 20 If that were indeed true, would that 21 change your opinion that the Ultrapro mesh 22 ultimately failed as a sling in cadaver labs? 23 A. If they fixed the sticking to the sheath 24 problem, but not how thin the sling is and its</p> |

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| <p style="text-align: right;">Page 46</p> <p>1 inability to handle the stress at the urethra, no, 2 it would not change my opinion. 3 Q. If, after making changes to the TVT 4 product which used the Ultrapro mesh after these 5 cadaver labs, the product was reevaluated and was 6 not rejected by two-thirds of surgeons using the 7 device, would that change any of your opinions in 8 this case? 9 MS. SMITH: Object to form. 10 BY THE WITNESS: 11 A. I would still not say it's adequate 12 without being tested clinically. 13 BY MR. FAES: 14 Q. But would it change your opinion 15 regarding whether it was rejected by two-thirds of 16 surgeons as a sling concept if a later -- if a 17 later evaluation by surgeons actually found a much 18 higher acceptance rate? 19 MS. SMITH: Object to form. 20 BY THE WITNESS: 21 A. It might. I would have to see what they 22 said. 23 BY MR. FAES: 24 Q. Let me ask you this: Are you familiar</p> | <p style="text-align: right;">Page 48</p> <p>1 Q. If they did, would that change any of 2 your opinions in this case regarding the use of 3 Ultrapro in a sling? 4 MS. SMITH: Object. 5 BY THE WITNESS: 6 A. If -- sorry. Go ahead. 7 MS. SMITH: Object to form. 8 BY THE WITNESS: 9 A. If Ethicon employees said it was 10 substantially equivalent, no, that would not change 11 my opinion. 12 BY MR. FAES: 13 Q. If Ethicon employees told the FDA that 14 the TVT-O-PA sling was substantially equivalent to 15 the TVT-O, would that change any of your opinions 16 in this case regarding the use of the Ultrapro mesh 17 in the sling? 18 A. No. 19 MS. SMITH: Object to form. 20 BY MR. FAES: 21 Q. Have you seen any studies in the 22 published literature utilizing the Ultrapro mesh 23 for the treatment of stress urinary incontinence in 24 patients?</p> |
| <p style="text-align: right;">Page 47</p> <p>1 with the TVT-O-PA or, as it's also called, the TOPA 2 product? 3 A. The TOPA? 4 Q. Um-hmm. 5 A. That's an Ethicon product? 6 Q. Yes. 7 A. No. 8 Q. Are you familiar with it? You're not 9 familiar with it? 10 A. No. 11 Q. Well, I'll represent to you that the 12 TVT-O-PA or TOPA product was a product being 13 developed by Ethicon for the treatment of stress 14 urinary incontinence which utilized the Ultrapro 15 mesh rather than the standard polypropylene mesh 16 that's used in the TVT. Okay? 17 So, assuming that to be true, do you 18 know whether or not professionals at Ethicon 19 described the TVT-O-PA as substantially equivalent 20 to the TVT-O? 21 MS. SMITH: Object to form. 22 BY THE WITNESS: 23 A. I don't know. 24 BY MR. FAES:</p> | <p style="text-align: right;">Page 49</p> <p>1 A. Not that I recall. 2 Q. Are you familiar with the Scion product 3 that was developed by Ethicon, S-c-i-o-n? 4 A. Is that a car? 5 Q. I think it's also a car, but it's also a 6 TVT-O sling that was under development by Ethicon. 7 A. No. 8 Q. Your answer is no. Were you ever 9 invited to evaluate the TVT-O-PA sling in a cadaver 10 lab by Ethicon? 11 A. Not that I know of. 12 Q. Do you know whether or not Ethicon did 13 indeed invite many people who were preceptors at 14 the time like yourself to evaluate the TVT-O-PA 15 product in cadaver labs? 16 A. I don't know. 17 Q. Same question on Scion. I'm assuming 18 since you don't know what it is -- well, they might 19 not have told you the name. 20 Were you ever invited by Ethicon to 21 evaluate the Scion prototype in any cadaver labs? 22 A. Not that I recall. 23 Q. Were you ever invited by Ethicon to 24 evaluate any prototypes for the treatment of stress</p> |

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| <p style="text-align: right;">Page 50</p> <p>1 urinary incontinence in cadaver labs?</p> <p>2 A. Not that I recall.</p> <p>3 Q. Doctor, on page 37 of your report you</p> <p>4 state that you've reviewed photographs of the mesh</p> <p>5 being stretched 50% and it's your opinion that this</p> <p>6 is a laboratory scenario as the mesh is not</p> <p>7 similarly stretched during implantation.</p> <p>8 Do you see that?</p> <p>9 A. Yes.</p> <p>10 Q. Is that an opinion you intend to offer</p> <p>11 in this case?</p> <p>12 A. Yes.</p> <p>13 Q. And you believe you can offer that</p> <p>14 opinion to a reasonable degree of medical</p> <p>15 certainty?</p> <p>16 A. Yes.</p> <p>17 Q. What amount of stress do you believe the</p> <p>18 TVT or TVT-O mesh is subjected to during</p> <p>19 implantation?</p> <p>20 A. And are you asking how much does it</p> <p>21 stress or how much pressure is put on it?</p> <p>22 Q. Let's first start with how much do you</p> <p>23 believe it stretches during implantation?</p> <p>24 A. It should stretch minimally, if at all.</p> | <p style="text-align: right;">Page 52</p> <p>1 very -- it's very difficult to stretch it, to move</p> <p>2 it even if you try.</p> <p>3 Q. So, you believe it can stretch, but it's</p> <p>4 difficult, correct?</p> <p>5 A. Yes.</p> <p>6 Q. Do you believe -- strike that.</p> <p>7 Do you have an opinion on what</p> <p>8 percentage the mesh does actually stretch once it's</p> <p>9 placed in the human body?</p> <p>10 MS. SMITH: Did you say percentage?</p> <p>11 MR. FAES: Yes.</p> <p>12 MS. SMITH: Object to form.</p> <p>13 BY THE WITNESS:</p> <p>14 A. No.</p> <p>15 BY MR. FAES:</p> <p>16 Q. You don't have a percent -- strike that.</p> <p>17 You don't have an opinion on how much</p> <p>18 the TVT mesh elongates when it's surgically placed</p> <p>19 in terms of percentage, correct?</p> <p>20 MS. SMITH: Object to form.</p> <p>21 BY THE WITNESS:</p> <p>22 A. Correct.</p> <p>23 BY MR. FAES:</p> <p>24 Q. And you don't have any opinion on what</p> |
| <p style="text-align: right;">Page 51</p> <p>1 Q. Do you know what percentage -- you say</p> <p>2 minimally. Strike that.</p> <p>3 You say minimally. Do you have a</p> <p>4 percentage in mind of the percentage that you think</p> <p>5 it stretches during implantation?</p> <p>6 A. No.</p> <p>7 MS. SMITH: Object to form.</p> <p>8 BY MR. FAES:</p> <p>9 Q. Same question regarding stretch in the</p> <p>10 human body. How much stretch do you think the TVT</p> <p>11 mesh is subjected to once it's placed in the human</p> <p>12 body?</p> <p>13 MS. SMITH: Object to form.</p> <p>14 BY THE WITNESS:</p> <p>15 A. Do you mean not during implantation?</p> <p>16 BY MR. FAES:</p> <p>17 Q. Correct. Not during the procedure.</p> <p>18 After implantation once it's in there.</p> <p>19 A. So, after it's implanted, can it</p> <p>20 stretch?</p> <p>21 Q. Yes. First of all, can it stretch?</p> <p>22 A. No.</p> <p>23 Q. You don't believe it can stretch at all?</p> <p>24 A. I believe it can stretch, but it's</p> | <p style="text-align: right;">Page 53</p> <p>1 percentage the TVT mesh may stretch once it's in</p> <p>2 the human body in terms of percentage, correct?</p> <p>3 A. Correct.</p> <p>4 Q. Do you have an opinion as to the amount</p> <p>5 of force that the TVT mesh is subjected to during</p> <p>6 implantation?</p> <p>7 A. I would have to look at references, but</p> <p>8 I don't have that at the top of my head right now.</p> <p>9 Q. Do you have an opinion of how much force</p> <p>10 the TVT mesh is subjected to once it is placed in</p> <p>11 the body?</p> <p>12 A. Same answer.</p> <p>13 MR. FAES: Can I go off the record. I think I</p> <p>14 have got like literally five minutes or less than</p> <p>15 five minutes. I want to get organized for three</p> <p>16 minutes and then go back on. Is that okay?</p> <p>17 MS. SMITH: Yes.</p> <p>18 MR. FAES: Okay. Let's just go off the record</p> <p>19 for just a second.</p> <p>20 (WHEREUPON, a recess was had</p> <p>21 from 9:00 to 9:03 a.m.)</p> <p>22 BY MR. FAES:</p> <p>23 Q. Doctor, we're back on the record after a</p> <p>24 short break. Are you ready to proceed?</p> |

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| <p style="text-align: right;">Page 54</p> <p>1 A. Yes.</p> <p>2 Q. Doctor, would you agree that it's</p> <p>3 important to have a mesh that's compliant with</p> <p>4 vaginal tissues for the treatment of stress urinary</p> <p>5 incontinence?</p> <p>6 MS. SMITH: Object to form.</p> <p>7 BY THE WITNESS:</p> <p>8 A. Yes.</p> <p>9 BY MR. FAES:</p> <p>10 Q. In fact, you want the mesh to elongate</p> <p>11 and mimic the natural vaginal tissues, correct?</p> <p>12 A. We want it to have some elasticity,</p> <p>13 correct.</p> <p>14 Q. In fact, you believe that the elasticity</p> <p>15 of the TVT-O -- strike that.</p> <p>16 You believe that the elasticity of the</p> <p>17 TVT device is in fact one of the things that makes</p> <p>18 it successful. Would you agree with that?</p> <p>19 A. Yes.</p> <p>20 Q. Would you agree with me that if</p> <p>21 polypropylene meshes are different, that the data</p> <p>22 can't be transferred from one mesh to the other?</p> <p>23 MS. SMITH: Object to form.</p> <p>24 BY THE WITNESS:</p> | <p style="text-align: right;">Page 56</p> <p>1 whether or not laser-cut mesh is stiffer and less</p> <p>2 safe than mechanically-cut mesh?</p> <p>3 A. I don't know.</p> <p>4 Q. Would the results of such a study, if it</p> <p>5 were done, be important to you?</p> <p>6 A. It would depend on the study.</p> <p>7 Q. Would you agree that if the study were</p> <p>8 done correctly and appropriately and the study</p> <p>9 showed that there was indeed a difference between</p> <p>10 the safeness of the mechanically-cut mesh and the</p> <p>11 laser-cut mesh, the results would be important to</p> <p>12 you?</p> <p>13 MS. SMITH: Object to form.</p> <p>14 BY THE WITNESS:</p> <p>15 A. Again, I would need to see the study to</p> <p>16 see if I thought it was clinically relevant because</p> <p>17 it could be performed correctly and still not have</p> <p>18 clinical meaning.</p> <p>19 BY MR. FAES:</p> <p>20 Q. Would you agree that if there was ever a</p> <p>21 study where the primary endpoint was to determine</p> <p>22 whether or not the laser-cut mesh is stiffer and</p> <p>23 less safe than the mechanically-cut mesh, that the</p> <p>24 results of such a study could potentially be</p> |
| <p style="text-align: right;">Page 55</p> <p>1 A. Yes.</p> <p>2 BY MR. FAES:</p> <p>3 Q. For example, if a mesh is three times</p> <p>4 stiffer than another mesh, the clinical data from</p> <p>5 the less stiff mesh cannot be used to support the</p> <p>6 safety and efficacy of the stiffer mesh. Would you</p> <p>7 agree with that?</p> <p>8 MS. SMITH: Object to form.</p> <p>9 BY THE WITNESS:</p> <p>10 A. I think, yeah, I agree that you need to</p> <p>11 collect data on the different types of mesh.</p> <p>12 BY MR. FAES:</p> <p>13 Q. Would you agree that meshes with higher</p> <p>14 stiffness have the potential to increase tissue</p> <p>15 erosions in the treatment of stress urinary</p> <p>16 incontinence?</p> <p>17 MS. SMITH: Object to form.</p> <p>18 BY THE WITNESS:</p> <p>19 A. Has the potential.</p> <p>20 BY MR. FAES:</p> <p>21 Q. Do you know if Ethicon has ever done a</p> <p>22 study where the primary endpoint is -- strike that.</p> <p>23 Do you know if Ethicon has ever done a</p> <p>24 study where the primary endpoint is to determine</p> | <p style="text-align: right;">Page 57</p> <p>1 important to you depending what the results were?</p> <p>2 MS. SMITH: Object to form.</p> <p>3 BY THE WITNESS:</p> <p>4 A. Potentially.</p> <p>5 BY MR. FAES:</p> <p>6 Q. Doctor, do you know what the standard is</p> <p>7 that a manufacturer must follow in designing mesh</p> <p>8 products?</p> <p>9 A. No.</p> <p>10 Q. Do you know what responsibilities a</p> <p>11 manufacturer holds in designing mesh products?</p> <p>12 MS. SMITH: Object to form.</p> <p>13 BY THE WITNESS:</p> <p>14 A. No.</p> <p>15 BY MR. FAES:</p> <p>16 Q. Do you know what kinds of things a</p> <p>17 company researches before a product is designed or</p> <p>18 released?</p> <p>19 A. No.</p> <p>20 Q. Would you agree that surgery rates for</p> <p>21 stress urinary incontinence have increased since</p> <p>22 the introduction of the TVT?</p> <p>23 A. Yes.</p> <p>24 Q. Would you agree that your surgery rate</p> |

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| <p style="text-align: right;">Page 58</p> <p>1 increased following your adoption of the TVT?</p> <p>2 MS. SMITH: Object to form.</p> <p>3 BY THE WITNESS:</p> <p>4 A. Not necessarily.</p> <p>5 BY MR. FAES:</p> <p>6 Q. Would you agree your surgery rate for</p> <p>7 stress urinary incontinence increased following</p> <p>8 your adoption of the TVT?</p> <p>9 MS. SMITH: Object to form.</p> <p>10 BY THE WITNESS:</p> <p>11 A. I have to answer that without a yes or a</p> <p>12 no. It also was introduced early in my career when</p> <p>13 my volumes were increasing anyway, so I wouldn't</p> <p>14 want you to say that they increased because of TVT.</p> <p>15 I think TVT sped up the process for how</p> <p>16 long we waited for a woman to have severe</p> <p>17 incontinence before we offered surgery but not</p> <p>18 necessarily the overall volume in my practice.</p> <p>19 BY MR. FAES:</p> <p>20 Q. Let me ask you this way. If a physician</p> <p>21 were solely doing the laparoscopic Burch procedure</p> <p>22 for the treatment of stress urinary incontinence,</p> <p>23 it's unlikely that that surgeon could -- would be</p> <p>24 physically able to do as many surgeries as a</p> | <p style="text-align: right;">Page 60</p> <p>1 you talking about TVT-Retropubic or TVT-Obturator</p> <p>2 because those are a bit different?</p> <p>3 MS. SMITH: With all due respect.</p> <p>4 MR. FAES: One last question.</p> <p>5 MS. SMITH: This isn't anything new or updated</p> <p>6 since her last.</p> <p>7 MR. FAES: I'm going to ask one more question.</p> <p>8 MS. SMITH: If it's updated, but if it's going</p> <p>9 back and rehashing, no.</p> <p>10 MR. FAES: I don't think it's rehashing. I</p> <p>11 don't think she's been asked this. It's my last</p> <p>12 question.</p> <p>13 MS. SMITH: I know, but the point is you're</p> <p>14 only supposed to be dealing with new information</p> <p>15 since your last deposition. But ask it and let's</p> <p>16 see.</p> <p>17 BY MR. FAES:</p> <p>18 Q. Do you know whether or not there is a</p> <p>19 difference in the way a mechanically cut TVT mesh</p> <p>20 should be tensioned versus a laser-cut TVT mesh?</p> <p>21 A. No.</p> <p>22 Q. So, you believe they should be tensioned</p> <p>23 the same?</p> <p>24 A. Yes.</p> |
| <p style="text-align: right;">Page 59</p> <p>1 physician who primarily used TVT for the treatment</p> <p>2 of stress urinary incontinence, correct?</p> <p>3 A. Well, you can't do as many in an OR day,</p> <p>4 but it also depends how many patients you are</p> <p>5 seeing in the practice, how many are presenting</p> <p>6 with the problem.</p> <p>7 MS. SMITH: You are down to your two.</p> <p>8 MR. FAES: Two questions or two minutes?</p> <p>9 MS. SMITH: Two questions. Whatever.</p> <p>10 BY MR. FAES:</p> <p>11 Q. Do you think that synthetic mesh</p> <p>12 products are designed to increase surgery rates?</p> <p>13 MS. SMITH: I'm sorry. Say that again.</p> <p>14 BY MR. FAES:</p> <p>15 Q. Do you think that synthetic mesh</p> <p>16 products are designed to increase surgery rates?</p> <p>17 MS. SMITH: Object to form.</p> <p>18 BY THE WITNESS:</p> <p>19 A. No.</p> <p>20 BY MR. FAES:</p> <p>21 Q. Doctor, what is the proper way to</p> <p>22 tension a TVT device?</p> <p>23 A. Well, there are a number of ways that</p> <p>24 are considered acceptable how to tension it. Are</p> | <p style="text-align: right;">Page 61</p> <p>1 MR. FAES: That's all the questions I have</p> <p>2 since I'm out of time. Thank you.</p> <p>3 MS. SMITH: No questions. She does want to</p> <p>4 read and sign.</p> <p>5 (Time Noted: 9:11 a.m.)</p> <p>6 FURTHER DEPONENT SAITH NAUGHT.</p> <p>7</p> <p>8</p> <p>9</p> <p>10</p> <p>11</p> <p>12</p> <p>13</p> <p>14</p> <p>15</p> <p>16</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> |

1 I, CORINNE T. MARUT, C.S.R. No. 84-1968,
2 Registered Professional Reporter and Certified
3 Shorthand Reporter, do hereby certify:
4 That previous to the commencement of the
5 examination of the witness, the witness was duly
6 sworn to testify the whole truth concerning the
7 matters herein;
8 That the foregoing deposition transcript
9 was reported stenographically by me, was thereafter
10 reduced to typewriting under my personal direction
11 and constitutes a true record of the testimony
12 given and the proceedings had;
13 That the said deposition was taken
14 before me at the time and place specified;
15 That the reading and signing by the
16 witness of the deposition transcript was agreed
17 upon as stated herein;
18 That I am not a relative or employee or
19 attorney or counsel, nor a relative or employee of
20 such attorney or counsel for any of the parties
21 hereto, nor interested directly or indirectly in
22 the outcome of this action.
23 It was requested before completion of
24 the deposition that the witness, DENISE ELSER,
25 M.D., have the opportunity to read and sign the
26 deposition transcript.

CORINNE T. MARUT, Certified Reporter

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3 Please read your deposition over
4 carefully and make any necessary corrections. You
5 should state the reason in the appropriate space on
6 the errata sheet for any corrections that are made.

7 After doing so, please sign the errata
8 sheet and date it.

9 You are signing same subject to the
10 changes you have noted on the errata sheet, which
11 will be attached to your deposition.

12 It is imperative that you return the
13 original errata sheet to the deposing attorney
14 within thirty (30) days of receipt of the
15 deposition transcript by you. If you fail to do
16 so, the deposition transcript may be deemed to be
17 accurate and may be used in court.

ERRATA

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ACKNOWLEDGMENT OF DEPONENT

I, DENISE ELSER, M.D., do hereby
certify under oath that I have read the foregoing
pages, and that the same is a correct transcription
of the answers given by me to the questions therein
propounded, except for the corrections or changes
in form or substance, if any, noted in the attached
Errata Sheet.

DENISE ELSER, M.D.

DATE _____

Subscribed and sworn
to before me this

_____ day of _____, 20____.

My commission expires:_____

Notary Public

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